REMARKS/ARGUMENTS

Claims 1-33 remain pending in this application. Applicant has amended Claims 1, 10, 11, 16, 28 and 33. Applicant submits that no new matter has been added by these amendments.

More specifically, support for the amendments to Claim 1 can be found, for example, in Figure 1; page 9, lines 11-17 and 20-24; page 10, lines 5-12; page 10, lines 13-23; page 11, lines 13-16 and Figures 5 and 6; page 12, line 17-page 13 line 4 and Figures 7 and 8; and page 13, lines 14-20 and Figures 9 and 10. Support for the amendments to Claims 10, 11 and 16 can be found, for example, at page 9, lines 2-6 and 12-16. Support for the amendments to Claims 28 and 33 can be found at Figure 1; page 10, lines 13-23 and Figures 5-6; page 11, lines 13-22, page 12, line 17-page 13, line 4, and Figures 7 and 8.

The Examiner has maintained the rejection of Claims 1 and 28 as being anticipated by Brignola, Claims 2-27 and 29-32 as being obvious over Landau in view of Landau et al. and further in view of Brignola, and Claim 33 as being inherently disclosed in Landau and Landau et al. For the reasons stated in its response of February 19, 2009 and prior responses, and the reasons stated herein, Applicant respectfully traverses the Examiner's rejections.

Claims 1 and 28 are not anticipated by Brignola under 35 USC 102

Claim 1

Brignola does not disclose an injection prevention component as claimed

Applicant has amended Claim 1 to clarify that the injection prevention component has a first injection prevention configuration to prevent the injector assembly from administering injectate to a subject at a sufficient pressure to pierce the skin. No element of Brignola prevents

the injector assembly of Brignola from administering injectate at a sufficient pressure to pierce the skin. Rather, as noted in Applicant's prior response, the thin diaphragm of Brignola is designed to fail as part of the injection process and not to prevent injection. Brignola simply does not disclose an injection prevention component as claimed by Applicant.

The diaphragm of Brignola is located within, not distal to, the injector lumen

In addition, Claim 1 has been amended to clarify that the distal end orifice is located distal to the injector lumen. This requires that the invention prevention component, which is disposed distal to the distal end orifice, is also located distal to the injector lumen. Even if the diaphragm of Brignola could arguably be construed to serve as an injection prevention component, the diaphragm is located within the injector lumen of the syringe assembly, and no part is located distal to the injector lumen as required by Claim 1.

The diaphragm of Brignola is not reversibly movable between a first and second configuration

Claim 1 has been further amended to specify that the injection prevention component has a first injection prevention configuration to prevent the injector assembly from administering an injectate and a second injection permitting configuration to permit the injector assembly to administer injectate, and that the injection prevention component is reversibly movable between the first configuration when the cap is removed and the second configuration when the cap is in place. In contrast, the diaphragm of Brignola is not reversibly movable between a first and second configuration. Rather, once the diaphragm is broken, it cannot be returned to its unbroken state. Further, the diaphragm of Brignola is not broken or otherwise movable between a first and second configuration in response to removal and placement of a cap.

Therefore, because Brignola does not disclose every element of Claim 1, Brignola cannot anticipate Claim 1 as presently amended.

Claim 28

Brignola does not disclose a means for preventing the injection piston from moving

As discussed in more detail in Applicant's prior response, the present Office Action does not identify how Brignola discloses a "means for preventing the injection piston from moving from a locked position to a discharged position" as recited in Claim 28. In fact, the Office Action does not even mention such limitation with respect to Brignola. If the Examiner maintains his rejection, Applicant respectfully requests that the Examiner indentify which elements of Brignola serve as a means for preventing the injection piston from moving from a locked position to a discharged position.

Brignola does not disclose such means distal to the injector lumen

Furthermore, even if such an element could arguably be construed to exist in Brignola, Claim 28 has been amended to clarify that the distal end orifice is distal to the injector lumen. Claim 28 requires that the means for preventing the injection piston from moving be partially located distal to the distal end orifice. There is no part of any element of Brignola located distal to the injector lumen that could serve as a means for preventing the injection piston from moving.

Brignola does not disclose a relationship between such means and a cap

Claim 28 has been further amended to specify that the means for preventing the injection piston from moving are in the locked position when the cap is removed and in the discharged

position when said cap is in place. Again, if a "means for preventing the injection piston from moving" could arguably be construed to exist in Brignola, there is no disclosure of a relationship between such element and the removal and placement of a cap as required by amended Claim 28.

Therefore, because Brignola does not disclose every element of Claim 28, Brignola cannot anticipate Claim 28 as presently amended.

Claims 2-27 and 29-32 are not obvious under 35 USC 103 over Landau, in view of Landau et al. and further in view of Brignola

Claims 2-27

Neither Landau, Landau et al. nor Brignola, alone or in combination, disclose the claimed injection prevention component

As discussed above, Applicant has amended Claim 1 to clarify that the injection prevention component has a first injection prevention configuration to prevent the injector assembly from administering injectate to a subject at a sufficient pressure to pierce the skin. In contrast, the plug member 44 of Landau is a seal to prevent leakage and does not prevent the injector assembly from administering injectate a high pressure. Rather, plug member 44 is dislodged by a small amount of hydraulic pressure caused by movement of the injection piston one thread pitch dimension, thereby **allowing** medication to flow around it and out of the injection orifice (Landau at 8:51-64 and 9:10-22). Thus, plug member 44 would similarly be displaced by injectate administered at a sufficient pressure to pierce the skin and **would not prevent** such administration.

In contrast to the Examiner's suggestions, Landau et al. does not teach that pistons and latches at the distal end of infusion systems are conventionally used to prevent the injection of an infusion system. The orifice shield, piston and latch of Landau et al. do not prevent the injection of an infusion system and therefore do not remedy the deficiencies of Landau. Rather, plug-like member, outlet valve 46, 246, 346 and 446 is a leak prevention component **displaced by hydraulic pressure**, thereby **allowing** injectate to flow around it and into a patient (Landau et al. at 6:24-35). Aluminum seal 568 and 566 of Landau et al. are similarly leak prevention components that are **burst apart by, rather than preventing, the high pressure injectate** (Landau et al. 6:51-60). As such, Landau et al. does not teach conventional elements for **preventing** the injection of an infusion system.

As discussed above, Brignola similarly does not disclose an injection prevention component as claimed.

Neither Landau, Landau et al. nor Brignola, alone or in combination, disclose an injection prevention component reversibly movable between a first injection prevention configuration when a cap is removed and a second injection permitting configuration when a cap is in place.

As discussed above, Claim 1 has been amended to specify that the injection prevention component has a first injection prevention configuration to prevent the injector assembly from administering an injectate and a second injection permitting configuration to permit the injector assembly to administer injectate, and that the injection prevention component is reversibly movable between the first configuration when the cap is removed and the second configuration when the cap is in place. None of the cited references disclose or suggest such an injection prevention component.

The plug member 44 of Landau is not reversibly movable between a first and second position. Rather, Landau shows a single-use jet injection cartridge in which a plug member 44 can be displaced prior to injection. Nothing in Landau discloses a mechanism for reversibly moving the plug member back to a first position and because Landau discloses a single-use cartridge, nothing in Landau suggests such a reversible movement. Furthermore, plug member 44 of Landau is moved from a first position to a second position by relative rotation of the two body portions of the device and not in response to placement of a cap.

Landau et al. does not remedy the failings of Landau. As in Landau, the plug-like member, outlet valve 46, 246, 346 and 446 of Landau et al. is not reversibly movable between a first and second position. Again, nothing in Landau et al. discloses or suggests that return of valve 46 to the first position is possible or desirable after use or upon removal of a cap. Further, the aluminum seal 558 and elastomeric membrane 566 of Landau et al., are not reversibly movable between a first and second configuration. Rather, once the seal or membrane is broken it cannot be returned to its unbroken state and cannot be reversibly movable between a first and second configuration in response to the removal and replacement of a cap.

Moreover, as discussed above, Brignola does not teach or suggest that the diaphragm disclosed therein is reversibly moveable between a first and second configuration.

Neither Landau, Landau et al, nor Brignola, alone or in combination, disclose an injection prevention component distal to the distal end orifice and injector lumen

As noted above, Claim 1, from which claims 2-27 depend, has been amended to clarify that the distal end orifice is distal to the injector lumen, such that the injection prevention component disposed distal to the distal end of the orifice is also distal to the injector lumen. As

discussed in the prior response and above, each of Landau and Landau et al. disclose leakage prevention features that are located entirely proximal to the distal end orifice, and Brignola discloses a diaphragm located entirely within the injector lumen. As such, none of the cited references disclose an injection prevention component distal to the distal end orifice and injector lumen.

Therefore, because the combination of Landau in view of Landau et al. and further in view of Brignola, does not teach or suggest every element of Claim 1, and Claims 2-27 which depend therefrom, Claims 1-27 are not rendered obvious.

Claims 29-32

Claim 28, from which Claims 29-32 depend, has been modified to require that the "means for preventing the injection piston from moving from a locked position to a discharged position" are in the locked position when the cap is removed and in the discharged position when the cap is in place. In contrast, the triggering mechanism of Landau is moved from a locked position to a discharge position in response to rotation of body portions 12b and 12c, not in response to placement of a cap.

Furthermore, nothing in Landau prevents the injection piston itself from moving, locking in place or having a locked position, and no portion of the trigger prevention means of Landau is located distal to the distal end orifice, as discussed in more detail in Applicant's prior response. Rather Landau discloses only a means for preventing actuation of the triggering mechanism, not preventing movement of the injection piston itself.

Further, as discussed in more detail in Applicant's prior response, neither the aluminum seal nor elastomeric membrane of Landau et al. serve as a means for preventing the injection piston from moving.

Moreover, as discussed above, Brignola does not disclose or teach "a means for preventing the injection piston from moving from a locked position to a discharged position wherein said means are partially located distal to the distal end orifice."

Therefore, because the combination of Landau in view of Landau et al. and further in view of Brignola does not teach or suggest every element of Claim 28, and Claims 28-32 which depend therefrom, Claims 28-32 are not rendered obvious.

The Method Steps of Claim 33 Are Not Inherent to Either Landau or Landau et al.

Claim 33 has been amended to clarify that the step of loading a cap onto a distal end of an injector having a distal end orifice thereby disengages the locking mechanism partially located distal to the distal end orifice, and that the step of removing the cap after injection thereby engages the locking mechanism.

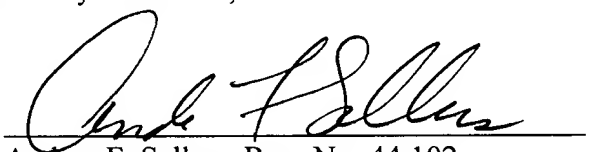
Neither Landau nor Landau et al. teach that removal of a cap thereby engages the locking mechanism. In fact, as discussed in more detail in the prior responses, neither Landau nor Landau et al. teach removal of a cap at all. Similarly, neither Landau nor Landau et al. teach a locking mechanism that is partially located distal to the distal end orifice as required by Claim 33.

Due to the deficiencies of Landau in view of Landau et al., the method of claim 33 cannot necessarily result from the apparatuses disclosed in Landau and Landau et al. as required for the references to inherently disclose the limitations of Claim 33.

In view of the foregoing amendments and remarks, it is respectfully submitted that the claims are now in condition for allowance and eventual issuance. Such action is respectfully requested. Should the Examiner have any further questions or comments which need be addressed in order to obtain allowance, please contact the undersigned attorney at the number listed below.

Acknowledgement of receipt is respectfully requested.

Respectfully submitted,

By: 

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